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Bard Peripheral Vascular, Inc.

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF ARIZONA

IN RE: Bard IVC Filters Products Liability Litigation	MDL NO. 15-02641-PHX-DGC
This Document Relates to:	
MICHAEL CALLAHAN and PRISCILLA CALLAHAN, Plaintiff, v. C. R. BARD, INC., a New Jersey Corporation; AND BARD PERIPHERAL VASCULAR INC., an Arizona Corporation, Defendants.	Case No. CV-15-2304-PHX-DGC **DEFENDANTS C. R. BARD, INC. AND BARD PERIPHERAL VASCULAR, INC.'S ANSWER AND AFFIRMATIVE DEFENSES AND DEMAND FOR TRIAL BY JURY**

Defendants C. R. Bard, Inc. ("Bard") and Bard Peripheral Vascular, Inc. ("BPV") (Bard and BPV are collectively "Defendants") answer the Complaint ("Plaintiffs' Complaint") of Plaintiffs Michael and Priscilla Callahan ("Plaintiffs") as follows:

INTRODUCTORY ALLEGATIONS

1. Defendants are without knowledge or information sufficient to form a truth as to the truth of the allegations contained in Paragraph 1 of Plaintiffs' Complaint and, on that basis, deny them.

2. Defendants are without knowledge or information sufficient to form a truth as to the truth of the allegations contained in Paragraph 2 of Plaintiffs' Complaint and, on that basis, deny them.

3. Defendants deny that Bard is a Delaware corporation. By way of further answer, Defendants admit that Bard is a New Jersey Corporation and that Bard is authorized to do business, and does business, in the State of New York, including Saratoga County. Defendants admit that Bard owns a facility where vena cava filters are manufactured, including filters that were manufactured under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 3 of Plaintiffs' Complaint.

4. Defendants admit that BPV is an Arizona Corporation and that BPV is authorized to do business, and does business, in the States of Colorado and New York, including Saratoga County, New York. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV has designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants further admit that BPV is a wholly owned subsidiary of Bard. Defendants deny any remaining allegations contained in Paragraph 4 of Plaintiffs' Complaint.

5. The allegations of Paragraph 5 of Plaintiffs' Complaint contain no factual allegations and, as a result, require no response by Defendants. However, to the extent Paragraph 5 purports to cast liability either directly or indirectly upon Defendants, said Paragraph is expressly denied.

JURISDICTION AND VENUE

6. Regarding Paragraph 6 of Plaintiffs' Complaint, Defendants do not contest that the injuries and damages alleged within Plaintiffs' Complaint exceed the jurisdictional limit of this Court. However, Defendants deny that they are liable to Plaintiffs for any amount whatsoever and deny that Plaintiffs have suffered any damages whatsoever. Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been, and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Northern District of New York.

7. The allegations contained in Paragraph 7 of Plaintiffs' Complaint are conclusions of law, which require no response. To the extent a response is required, Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been, and could not have been confirmed by Defendants, jurisdiction appears to be proper in the United States District Court for the Northern District of New York.

8. Regarding Paragraph 8 of Plaintiffs' Complaint, Defendants do not dispute that, based on the facts as alleged by Plaintiffs, which have not been and could not have been confirmed by Defendants, venue appears to be proper in the United States District Court for the Northern District of New York.

GENERAL FACTUAL ALLEGATIONS

9. Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market or the identity of manufacturers of inferior vena cava filters. Defendants deny any remaining allegations of Paragraph 9 of Plaintiffs' Complaint.

10. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may be designed for permanent placement, temporary placement, or both. Defendants deny any remaining allegations of Paragraph 10 of Plaintiffs' Complaint.

11. Defendants admit that the inferior vena cava is a large vein that receives blood from the lower regions of the body and delivers it to the right atrium of the heart. Defendants further admit that deep vein thrombosis and pulmonary emboli present dangerous risks to human health, including sometimes death. Defendants deny any remaining allegations of Paragraph 11 of Plaintiffs' Complaint.

12. Defendants admit that inferior vena cava filters are intended to prevent injury or death resulting from venous thrombosis and pulmonary embolism. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. The remaining allegations contained in Paragraph 12 of Plaintiffs' Complaint are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations.

13. Defendants deny the allegations contained in Paragraph 13 of Plaintiffs' Complaint.

14. Defendants admit that patients at a high risk for developing deep vein thrombosis and pulmonary embolism are frequently treated with anticoagulation therapy, including but not limited to the medications listed in Paragraph 14 of Plaintiffs' Complaint. Defendants further admit that inferior vena cava filters may also be used to treat patients who are at a high risk for developing deep vein thrombosis and pulmonary embolism. Defendants lack knowledge or information sufficient to form a belief as to the truth of any remaining allegations contained in Paragraph 14 of Plaintiffs' Complaint and, on that basis, deny them.

15. Defendants lack knowledge or information or information sufficient to form a belief as to the truth of the allegation regarding the time frame when inferior vena cava filters were first introduced on the market. Defendants also lack knowledge or information sufficient to form a belief as to the truth of the allegation regarding the time frame when optional or retrievable filters came to be marketed or the other allegations regarding optional or retrievable filters marketed by other manufacturers. Defendants admit that the Recovery® Filter was cleared by the FDA for optional use as a retrievable inferior vena cava filter.

Defendants deny any remaining allegations contained in Paragraph 15 of Plaintiffs' Complaint.

16. Defendants admit that Bard has distributed the Simon Nitinol Filter in the United States since at least 1992. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Recovery® Filter was developed in furtherance of those efforts. Defendants further admit that the Recovery® Filter was cleared by the FDA for optional use as a retrievable inferior vena cava filter. Defendants deny any remaining allegations contained in Paragraph 16 of Plaintiffs' Complaint.

17. Defendants deny the allegations contained in Paragraph 17 of Plaintiffs' Complaint.

18. Defendants deny the allegations contained in Paragraph 18 of Plaintiffs' Complaint.

19. Defendants deny the allegations contained in Paragraph 19 of Plaintiffs' Complaint.

20. Defendants admit that the Recovery® Filter was cleared by the FDA for permanent placement on November 27, 2002, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. The allegations contained in Footnote 1 regarding the 510(k) process are conclusions of law, to which no response is required. To the extent a response is required, Defendants deny those allegations. Defendants deny any remaining allegations contained in Paragraph 20 of Plaintiffs' Complaint, including any additional allegations in Footnote 1.

21. Defendants admit that the Recovery® Filter was cleared by the FDA for retrievable placement on July 25, 2003, pursuant to applications submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 21 of Plaintiffs' Complaint.

22. Defendants deny the allegations contained in Paragraph 22 of Plaintiffs' Complaint.

23. Defendants deny the allegations contained in Paragraph 23 of Plaintiffs' Complaint.

24. Defendants admit that the Recovery® Filter consists of twelve, shape-memory Nitinol wires emanating from a central Nitinol sleeve. Defendants further admit that the twelve wires form two levels of filtration for emboli: the legs provide the lower level of filtration, and the arms provide the upper level of filtration. Defendants deny any remaining allegations contained in Paragraph 24 of Plaintiffs' Complaint.

25. Defendants admit that the Recovery® Filter was designed to be inserted endovascularly. Defendants further admit that the Recovery® Filter is designed to be delivered via an introducer sheath, which is included in the delivery system for the device. Defendants deny any remaining allegations of Paragraph 25 of Plaintiffs' Complaint.

26. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Recovery® Filter was developed in furtherance of those efforts. Defendants deny the remaining allegations contained in Paragraph 26 of Plaintiffs' Complaint, including any sub-parts thereof.

27. Defendants deny the allegations contained in Paragraph 27 of Plaintiffs' Complaint.

28. Defendants deny the allegations contained in Paragraph 28 of Plaintiffs' Complaint.

29. Defendants deny the allegations contained in Paragraph 29 of Plaintiffs' Complaint, including all sub-parts thereof.

30. Defendants deny the allegations contained in Paragraph 30 of Plaintiffs' Complaint.

31. Defendants deny the allegations contained in Paragraph 31 of Plaintiffs' Complaint.

32. Defendants deny the allegations contained in Paragraph 32 of Plaintiffs' Complaint, including all sub-parts thereof.

33. Defendants deny the allegations contained in Paragraph 33 of Plaintiffs' Complaint, including all sub-parts thereof.

34. Defendants deny the allegations contained in Paragraph 34 of Plaintiffs' Complaint.

35. Defendants deny the allegations contained in Paragraph 35 of Plaintiffs' Complaint. By way of further response, Defendants admit that there are various well-documented complications that may occur as a result of the fracture, perforation, and/or migration of any inferior vena cava filter. Defendants further admit that it is well documented that many instances of filter fracture and/or migration result in no complications whatsoever but, rather, are completely asymptomatic. Bard further states that there are incidents related to the occurrence of known complications associated with every manufacturer of inferior vena cava filters. Defendants deny the remaining allegations of Paragraph 35 of Plaintiffs' Complaint.

36. Defendants deny the allegations contained in Paragraph 36 of Plaintiffs' Complaint, including all sub-parts thereof.

37. Defendants deny the allegations contained in Paragraph 37 of Plaintiffs' Complaint, including all sub-parts thereof.

38. Defendants deny the allegations contained in Paragraph 38 of Plaintiffs' Complaint.

39. Defendants deny the allegations contained in Paragraph 39 of Plaintiffs' Complaint.

40. Defendants deny the allegations contained in Paragraph 40 of Plaintiffs' Complaint as stated. Defendants state that, as part of their continuing efforts to constantly

evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. Defendants deny any remaining allegations contained in Paragraph 40 of Plaintiffs' Complaint.

41. Defendants deny the allegations contained in Paragraph 41 of Plaintiffs' Complaint.

42. Defendants deny the allegations contained in Paragraph 42 of Plaintiffs' Complaint.

43. Defendants deny the allegations contained in Paragraph 43 of Plaintiffs' Complaint.

44. Defendants deny the allegations contained in Paragraph 44 of Plaintiffs' Complaint.

45. Defendants deny the allegations contained in Paragraph 45 of Plaintiffs' Complaint.

46. Defendants deny the allegations contained in Paragraph 46 of Plaintiffs' Complaint.

47. Defendants deny the allegations contained in Paragraph 47 of Plaintiffs' Complaint. Defendants deny that the Recovery® Filter is unreasonably dangerous or defective in any manner. By way of further answer, Defendants state that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The G2® Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 47 of Plaintiffs' Complaint.

48. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the

Food, Drug and Cosmetic Act in 2005. Defendants deny any remaining allegations contained in Paragraph 48 of Plaintiffs' Complaint.

49. Defendants admit the G2® Filter System was cleared by the United States Food and Drug Administration for both permanent and retrievable use pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants further admit that the G2® Filter was originally cleared by the FDA for permanent use and was subsequently cleared in 2008 by the FDA for optional use as a retrievable inferior vena cava filter. Defendants deny any remaining allegations contained in Paragraph 49 of Plaintiffs' Complaint.

50. Defendants deny the allegations contained in Paragraph 50 of Plaintiffs' Complaint.

51. Defendants deny the allegations contained in Paragraph 51 of Plaintiffs' Complaint.

52. Defendants deny the allegations contained in Paragraph 52 of Plaintiffs' Complaint.

53. Defendants deny the allegations contained in Paragraph 53 of Plaintiffs' Complaint.

54. Defendants deny the allegations contained in Paragraph 54 of Plaintiffs' Complaint.

55. Defendants deny the allegations contained in Paragraph 55 of Plaintiffs' Complaint.

56. Defendants deny the allegations contained in Paragraph 56 of Plaintiffs' Complaint.

57. Defendants deny the allegations contained in Paragraph 57 of Plaintiffs' Complaint.

58. Defendants deny the allegations contained in Paragraph 58 of Plaintiffs' Complaint, including all sub-parts thereof.

59. Defendants deny the allegations contained in Paragraph 59 of Plaintiffs' Complaint, including all sub-parts thereof.

60. Defendants deny the allegations contained in Paragraph 60 of Plaintiffs' Complaint.

61. Defendants admit the G2® Express Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2008. Defendants further admit that the G2® Express Filter is similar to the G2® Filter, but includes a snare on the sheath of the filter to enhance retrievability. Defendants deny any remaining allegations contained in Paragraph 61 of Plaintiffs' Complaint.

62. Defendants deny that the G2® Filter is unreasonably dangerous or defective in any manner. Defendants admit that the Eclipse™ Filter System was cleared by the United States Food and Drug Administration pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act in 2010. Defendants further admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Eclipse™ Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 62 of Plaintiffs' Complaint.

63. Defendants deny the allegations contained in Paragraph 63 of Plaintiffs' Complaint.

64. Defendants deny the allegations contained in Paragraph 64 of Plaintiffs' Complaint, as stated. Defendants deny that the G2® Filter is unreasonably dangerous or defective in any manner. By way of further response, Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. In this regard, and pursuant to an application submitted under

Section 510(k) of the Food, Drug and Cosmetic Act, BPV received FDA clearance on August 24, 2011, for the Meridian® Filter. Defendants deny the remaining allegations of Paragraph 64 of Plaintiffs' Complaint.

65. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Meridian™ Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations of Paragraph 65 of Plaintiffs' Complaint.

66. Defendants deny the allegations contained in Paragraph 66 of Plaintiffs' Complaint.

67. Defendants deny the allegations contained in Paragraph 67 of Plaintiffs' Complaint.

68. Defendants deny the allegations contained in Paragraph 68 of Plaintiffs' Complaint.

69. Defendants deny that the G2® or Meridian™ Filter Systems were unreasonably dangerous or defective in any manner. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, and in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-saving performance of those devices. The Denali™ Filter was developed in furtherance of those efforts. Defendants further admit that the Denali™ Filter was cleared by the FDA for permanent placement on May 15, 2013, pursuant to an application submitted under Section 510(k) of the Food, Drug and Cosmetic Act. Defendants deny any remaining allegations contained in Paragraph 69 of Plaintiffs' Complaint.

70. Defendants deny that the G2® or G2® Express Filter Systems were unreasonably dangerous or defective in any manner. Defendants admit that, as part of their continuing efforts to constantly evaluate the medical devices they sell, and in conjunction with the ever-changing state-of-the-art, they are continually striving to improve the life-

saving performance of those devices. The Denali™ Filter was developed in furtherance of those efforts. Defendants deny any remaining allegations contained in Paragraph 70 of Plaintiffs' Complaint.

71. Defendants deny the allegations contained in Paragraph 71 of Plaintiffs' Complaint.

72. Defendants deny the allegations contained in Paragraph 72 of Plaintiffs' Complaint.

73. Defendants deny the allegations contained in Paragraph 73 of Plaintiffs' Complaint.

74. Defendants admit that Bard received a warning letter from the FDA's Los Angeles District Office dated July 13, 2015. Defendants deny the remaining allegations of Paragraph 74 of the Complaint as stated.

75. Defendants deny the allegations contained in Paragraph 75 of Plaintiffs' Complaint.

76. Defendants deny the allegations contained in Paragraph 76 of Plaintiffs' Complaint.

77. Defendants deny the allegations contained in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants deny the allegations contained in Paragraph 78 of Plaintiffs' Complaint.

79. Defendants deny the allegations contained in Paragraph 79 of Plaintiffs' Complaint.

80. Defendants deny the allegations contained in Paragraph 80 of Plaintiffs' Complaint.

81. Defendants deny the allegations contained in Paragraph 81 of Plaintiffs' Complaint.

82. Defendants deny the allegations contained in Paragraph 82 of Plaintiffs' Complaint.

83. Defendants deny the allegations contained in Paragraph 83 of Plaintiffs' Complaint.

FIRST CAUSE OF ACTION

NEGLIGENCE

84. Defendants incorporate by reference their responses to Paragraphs 1-83 of Plaintiffs' Complaint as if fully set forth herein.

85. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter Systems were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter Systems. Defendants deny any remaining allegations contained in Paragraph 85 of the Complaint.

86. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. Defendants deny any remaining allegations of Paragraph 86 of the Complaint.

87. The allegations contained in Paragraph 87 regarding Defendants' duty are legal conclusions of law, and no answer is required. To the extent a response is required, Defendants deny the allegations. Defendants deny any remaining allegations contained in Paragraph 87 of the Complaint.

88. Defendants deny the allegations contained in Paragraph 88 of Plaintiffs' Complaint.

89. Defendants deny the allegations contained in Paragraph 89 of Plaintiffs' Complaint.

90. Defendants deny the allegations contained in Paragraph 90 of Plaintiffs' Complaint.

91. Defendants deny the allegations contained in Paragraph 91 of Plaintiffs' Complaint.

92. Defendants deny the allegations contained in Paragraph 92 of Plaintiffs' Complaint, including all sub-parts thereof.

93. Defendants deny the allegations contained in Paragraph 93 of Plaintiffs' Complaint.

SECOND CAUSE OF ACTION

STRICT LIABILITY – FAILURE TO WARN

94. Defendants incorporate by reference their responses to Paragraphs 1-93 of Plaintiffs' Complaint as if fully set forth herein.

95. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 95 of Plaintiffs' Complaint.

96. Defendants deny the allegations contained in Paragraph 96 of Plaintiffs' Complaint.

97. Defendants deny the allegations contained in Paragraph 97 of Plaintiffs' Complaint.

98. Defendants deny the allegations contained in Paragraph 98 of Plaintiffs' Complaint.

99. Defendants deny the allegations contained in Paragraph 99 of Plaintiffs' Complaint.

100. Defendants deny the allegations contained in Paragraph 100 of Plaintiffs' Complaint.

101. Defendants deny the allegations contained in Paragraph 101 of Plaintiffs' Complaint.

102. Defendants deny the allegations contained in Paragraph 102 of Plaintiffs' Complaint.

103. Defendants deny the allegations contained in Paragraph 103 of Plaintiffs' Complaint.

104. Defendants deny the allegations contained in Paragraph 104 of Plaintiffs' Complaint.

105. Defendants deny the allegations contained in Paragraph 105 of Plaintiffs' Complaint.

106. Defendants deny the allegations contained in Paragraph 106 of Plaintiffs' Complaint.

107. Defendants deny the allegations contained in Paragraph 107 of Plaintiffs' Complaint.

108. Defendants deny the allegations contained in Paragraph 108 of Plaintiffs' Complaint.

109. Defendants deny the allegations contained in Paragraph 109 of Plaintiffs' Complaint.

THIRD CAUSE OF ACTION

STRICT LIABILITY – DESIGN DEFECT

110. Defendants incorporate by reference their responses to Paragraphs 1-109 of Plaintiffs' Complaint as if fully set forth herein.

111. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 111 of Plaintiffs' Complaint.

112. Defendants deny the allegations contained in Paragraph 112 of Plaintiffs' Complaint.

113. Defendants deny the allegations contained in Paragraph 113 of Plaintiffs' Complaint.

114. Defendants deny the allegations contained in Paragraph 114 of Plaintiffs' Complaint.

115. Defendants deny the allegations contained in Paragraph 115 of Plaintiffs' Complaint.

116. Defendants deny the allegations contained in Paragraph 116 of Plaintiffs' Complaint.

117. Defendants deny the allegations contained in Paragraph 117 of Plaintiffs' Complaint.

FOURTH CAUSE OF ACTION

STRICT LIABILITY – MANUFACTURING DEFECT

118. Defendants incorporate by reference their responses to Paragraphs 1-117 of Plaintiffs' Complaint as if fully set forth herein.

119. Defendants deny that the Meridian™ Filter System is unreasonably dangerous or defective in any manner. Defendants are without knowledge or information sufficient to

form a belief as to the truth of the allegations regarding the trade name of any inferior vena cava filter implanted in Plaintiff and, on that basis, deny them. By way of further response, Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 119 of Plaintiffs' Complaint.

120. Defendants deny the allegations contained in Paragraph 120 of Plaintiffs' Complaint.

121. Defendants deny the allegations contained in Paragraph 121 of Plaintiffs' Complaint.

122. Defendants deny the allegations contained in Paragraph 122 of Plaintiffs' Complaint.

FIFTH CAUSE OF ACTION

BREACH OF EXPRESS WARRANTY

123. Defendants incorporate by reference their responses to Paragraphs 1-122 of Plaintiffs' Complaint as if fully set forth herein.

124. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 124 of Plaintiffs' Complaint.

125. Defendants deny the allegations contained in Paragraph 125 of Plaintiffs' Complaint.

126. Defendants deny the allegations contained in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants deny the allegations contained in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants deny the allegations contained in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants deny the allegations contained in Paragraph 129 of Plaintiffs' Complaint.

130. Defendants deny the allegations contained in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants deny the allegations contained in Paragraph 131 of Plaintiffs' Complaint.

132. Defendants deny the allegations contained in Paragraph 132 of Plaintiffs' Complaint.

133. Defendants deny the allegations contained in Paragraph 133 of Plaintiffs' Complaint.

SIXTH CAUSE OF ACTION

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY AND FITNESS

134. Defendants incorporate by reference their responses to Paragraphs 1-133 of Plaintiffs' Complaint as if fully set forth herein.

135. Defendants admit that Bard owns a facility where vena cava filters are manufactured and that filters under the trademark Meridian™ Filter System were manufactured at that facility. Defendants further admit that BPV designs, sells, markets, and distributes inferior vena cava filters and that BPV designed, sold, marketed, and distributed filters under the trademark Meridian™ Filter System. Defendants deny any remaining allegations contained in Paragraph 135 of Plaintiffs' Complaint.

136. Defendants deny the allegations contained in Paragraph 136 of Plaintiffs' Complaint.

137. Defendants deny the allegations contained in Paragraph 137 of Plaintiffs' Complaint.

138. Defendants deny the allegations contained in Paragraph 138 of Plaintiffs' Complaint, including all sub-parts thereof.

139. Defendants deny the allegations contained in Paragraph 139 of Plaintiffs' Complaint.

140. Defendants deny the allegations contained in Paragraph 140 of Plaintiffs' Complaint.

141. Defendants deny the allegations contained in Paragraph 141 of Plaintiffs' Complaint.

142. Defendants deny the allegations contained in Paragraph 142 of Plaintiffs' Complaint.

SEVENTH CAUSE OF ACTION

FRAUD AND FRAUDULENT CONCEALMENT

143. Defendants incorporate by reference their responses to Paragraphs 1-142 of Plaintiffs' Complaint as if fully set forth herein.

144. Defendants deny the allegations contained in Paragraph 144 of Plaintiffs' Complaint.

145. Defendants deny the allegations contained in Paragraph 145 of Plaintiffs' Complaint.

146. Defendants deny the allegations contained in Paragraph 146 of Plaintiffs' Complaint.

147. Defendants deny the allegations contained in Paragraph 147 of Plaintiffs' Complaint.

148. Defendants deny the allegations contained in Paragraph 148 of Plaintiffs' Complaint.

149. Defendants deny the allegations contained in Paragraph 149 of Plaintiffs' Complaint.

150. Defendants deny the allegations contained in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants deny the allegations contained in Paragraph 151 of Plaintiffs' Complaint.

EIGHTH CAUSE OF ACTION

LOSS OF CONSORTIUM

152. Defendants incorporate by reference their responses to Paragraphs 1-151 of Plaintiffs' Complaint as if fully set forth herein.

153. Defendants deny the allegations contained in Paragraph 153 of Plaintiffs' Complaint.

PRAYER FOR RELIEF

Furthermore, responding to the unnumbered Paragraph, including sub-parts, following the heading "PRAYER FOR RELIEF" and beginning "WHEREFORE," Defendants deny the allegations contained in such Paragraph and all sub-parts thereof.

Defendants further deny each and every allegation not specifically admitted herein.

DEFENSES

Defendants allege as affirmative defenses the following:

1. Plaintiffs' Complaint filed herein fails to state a claim or claims upon which relief can be granted under Rule 12 of the Federal Rules of Civil Procedure.

2. The sole proximate cause of Plaintiffs' damages, if any were sustained, was the negligence of a person or persons or entity for whose acts or omissions Defendants were and are in no way liable.

3. Plaintiffs' claims are barred, in whole or in part, by the applicable statutes of limitations and/or statute of repose.

4. If Plaintiffs have been damaged, which Defendants deny, any recovery by Plaintiffs is barred to the extent Plaintiffs voluntarily exposed themselves to a known risk and/or failed to mitigate their alleged damages. To the extent Plaintiffs have failed to mitigate their alleged damages, any recovery shall not include alleged damages that could have been avoided by reasonable care and diligence.

5. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of Plaintiffs.

6. If Plaintiffs have been damaged, which Defendants deny, such damages were caused by the negligence or fault of persons and/or entities for whose conduct Defendants are not legally responsible.

7. The conduct of Defendants and the subject product at all times conformed with the Federal Food, Drug and Cosmetics Act, 21 U.S.C. § 301, *et seq.*, and other pertinent federal statutes and regulations. Accordingly, Plaintiffs' claims are barred, in whole or in part, under the doctrine of federal preemption, and granting the relief requested would impermissibly infringe upon and conflict with federal laws, regulations, and policies in violation of the Supremacy Clause of the United States Constitution.

8. If Plaintiff has been damaged, which Defendants deny, such damages were caused by unforeseeable, independent, intervening, and/or superseding events for which Defendants are not legally responsible.

9. There was no defect in the product at issue with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

10. If there were any defect in the products – and Defendants deny that there were any defects – nevertheless, there was no causal connection between any alleged defect and the product on the one hand and any damage to Plaintiffs on the other with the result that Plaintiffs are not entitled to recover against Defendants in this cause.

11. Plaintiffs' injuries, losses or damages, if any, were caused by or contributed to by other persons or entities that are severally liable for all or part of Plaintiffs' alleged injuries, losses or damages. If Defendants are held liable to Plaintiffs, which liability is specifically denied, Defendants are entitled to contribution, set-off, and/or indemnification, either in whole or in part, from all persons or entities whose negligence or fault proximately caused or contributed to cause Plaintiffs' alleged damages.

12. Plaintiffs' claims are barred to the extent that the injuries alleged in the Plaintiffs' Complaint were caused by the abuse, misuse, abnormal use, or use of the product at issue in a manner not intended by Defendants and over which Defendants had no control.

13. Plaintiffs' claims are barred to the extent that the injuries alleged in the Plaintiffs' Complaint were caused by a substantial change in the product after leaving the possession, custody, and control of Defendants.

14. Plaintiffs' breach of warranty claims are barred because: (1) Defendants did not make any warranties, express or implied, to Plaintiffs; (2) there was a lack of privity between Defendants and Plaintiffs; and (3) notice of an alleged breach was not given to the seller or Defendants.

15. Plaintiffs' claims for breach of implied warranty must fail because the product was not used for its ordinary purpose.

16. Defendants neither had nor breached any alleged duty to warn with respect to the product, with the result that Plaintiffs are not entitled to recover in this cause.

17. Plaintiffs' claims are barred by Defendants' dissemination of legally adequate warnings and instructions to learned intermediaries.

18. At all relevant times, herein, Plaintiffs' physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the subject product.

19. If Plaintiffs have been damaged, which Defendants deny, the actions of persons or entities for whose conduct Defendants are not legally responsible and the independent

knowledge of these persons or entities of the risks inherent in the use of the product and other independent causes, constitute an intervening and superseding cause of Plaintiffs' alleged damages.

20. To the extent that injuries and damages sustained by Plaintiffs, as alleged in Plaintiffs' Complaint, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiffs not found in the general public, they were unknown, unknowable, or not reasonably foreseeable to Defendants.

21. Defendants believe, and upon that ground allege, that Plaintiffs were advised of the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and voluntarily assumed them. Pursuant to the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars in whole or in part the damages that Plaintiffs seek to recover herein.

22. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

23. Plaintiffs' claims are barred because Plaintiffs suffered no injury or damages as a result of the alleged conduct and do not have any right, standing, or competency to maintain claims for damages or other relief.

24. Plaintiffs' claims are barred, in whole or in part, by the doctrines of waiver, estoppel, and/or laches.

25. If Plaintiffs suffered any damages or injuries, which is denied, Defendants state that Plaintiffs' recovery is barred, in whole or in part, or subject to reduction, under the doctrines of contributory and/or comparative negligence.

26. In the further alternative, and only in the event that it is determined that Plaintiffs are entitled to recover against Defendants, recovery should be reduced in proportion

to the degree or percentage of negligence, fault or exposure to products attributable to Plaintiffs, any other defendants, third-party defendants, or other persons, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the future.

27. Should Defendants be held liable to Plaintiffs, which liability is specifically denied, Defendants would be entitled to a setoff for the total of all amounts paid to Plaintiffs from all collateral sources.

28. Plaintiffs' claims may be barred, in whole or in part, from seeking recovery against Defendants pursuant to the doctrines of res judicata, collateral estoppel, release of claims, and the prohibition on double recovery for the same injury.

29. The injuries and damages allegedly sustained by Plaintiffs may be due to the operation of nature or idiosyncratic reaction(s) and/or pre-existing condition(s) in Plaintiffs over which Defendants had no control.

30. The conduct of Defendants and all activities with respect to the subject product have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

31. Defendants assert any and all defenses, claims, credits, offsets, or remedies provided by the Restatements (Second and Third) of Torts and reserve the right to amend their Answer to file such further pleadings as are necessary to preserve and assert such defenses, claims, credits, offsets, or remedies.

32. The device at issue complied with any applicable product safety statute or administrative regulation, and therefore Plaintiffs' defective design and warnings-based claims are barred under the Restatement (Third) of Torts: Products Liability § 4, *et seq.* and comments thereto.

33. Plaintiffs cannot show that any reasonable alternative design would have rendered the Meridian™ Filter inferior vena cava filter device as alleged in Plaintiffs' Complaint to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. f, nor could Defendants have known of any alternative design that may be identified by Plaintiffs.

34. The device at issue was not sold in a defective condition unreasonably dangerous to the user or consumer, and therefore Plaintiffs' claims are barred under the Restatement (Second) of Torts: Products Liability § 402A and comments thereto, and comparable provisions of the Restatement (Third) of Torts (Products Liability).

35. At all relevant times during which the device at issue was designed, developed, manufactured, and sold, the device was reasonably safe and reasonably fit for its intended use, was not defective or unreasonably dangerous, and was accompanied by proper warnings, information, and instructions, all pursuant to generally recognized prevailing industry standards and state-of-the-art in existence at the time.

36. Defendants specifically plead all affirmative defenses under the Uniform Commercial Code ("UCC") now existing or which may arise in the future, including those defenses provided by UCC §§ 2-607 and 2-709.

37. Plaintiffs' alleged damages, if any, should be apportioned among all parties at fault, and any non-parties at fault, pursuant to the Uniform Contribution Among Tortfeasors Act.

38. No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive damages is barred.

39. To the extent the claims asserted in Plaintiffs' Complaint are based on a theory providing for liability without proof of defect and proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the New York Constitution.

40. To the extent Plaintiffs seek punitive damages, Defendants specifically incorporate by reference any and all standards of limitations regarding the determination and/or enforceability of punitive damages awards that arose in the decisions of *BMW of No. America v. Gore*, 517 U.S. 559 (1996); *Cooper Industries, Inc. v. Leatherman Tool Group, Inc.*, 532 U.S. 424 (2001); *State Farm Mut. Auto Ins. Co. v. Campbell*, 123 S. Ct. 1513 (2003); and *Exxon Shipping Co. v. Baker*, No. 07-219, 2008 U.S. LEXIS 5263 (U.S. June 25, 2008) and their progeny as well as other similar cases under both federal and state law.

41. Any of Plaintiffs' claims for punitive or exemplary damages violate, and are therefore barred by, the Fourth, Fifth, Sixth, Eighth and Fourteenth Amendments to the Constitution of the United States of America, and similar provisions of the New York Constitution, on grounds including the following:

(a) it is a violation of the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution to impose punitive damages, which are penal in nature, against a civil defendant upon the plaintiffs satisfying a burden of proof which is less than the "beyond a reasonable doubt" burden of proof required in criminal cases;

(b) the procedures pursuant to which punitive damages are awarded may result in the award of joint and several judgments against multiple defendants for different alleged acts of wrongdoing, which infringes upon the Due Process and Equal Protection Clauses of the Fourteenth Amendment of the United States Constitution;

(c) the procedures to which punitive damages are awarded fail to provide a reasonable limit on the amount of the award against Defendants, which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(d) the procedures pursuant to which punitive damages are awarded fail to provide specific standards for the amount of the award of punitive damages which thereby violates the Due Process Clause of the Fourteenth Amendment of the United States Constitution;

(e) the procedures pursuant to which punitive damages are awarded result in the imposition of different penalties for the same or similar acts, and thus violate the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(f) the procedures pursuant to which punitive damages are awarded permit the imposition of punitive damages in excess of the maximum criminal fine for the same or similar conduct, which thereby infringes upon the Due Process Clause of the Fifth and Fourteenth Amendments and the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution;

(g) the procedures pursuant to which punitive damages are awarded permit the imposition of excessive fines in violation of the Eighth Amendment of the United States Constitution;

(h) the award of punitive damages to the plaintiff in this action would constitute a deprivation of property without due process of law; and

(i) the procedures pursuant to which punitive damages are awarded permit the imposition of an excessive fine and penalty.

42. Defendants expressly reserve the right to raise as an affirmative defense that Plaintiffs have failed to join all parties necessary for a just adjudication of this action, should discovery reveal the existence of facts to support such defense.

43. Defendants reserve the right to raise such other affirmative defenses as may be available or apparent during discovery or as may be raised or asserted by other defendants in this case. Defendants have not knowingly or intentionally waived any applicable affirmative defense. If it appears that any affirmative defense is or may be applicable after Defendants

have had the opportunity to conduct reasonable discovery in this matter, Defendants will assert such affirmative defense in accordance with the Federal Rules of Civil Procedure.

REQUEST FOR JURY TRIAL

Defendants C. R. Bard, Inc. and Bard Peripheral Vascular, Inc. demand a trial by jury on all issues appropriate for jury determination.

WHEREFORE, Defendants aver that Plaintiff is not entitled to the relief demanded in the Plaintiffs' Complaint, and these Defendants, having fully answered, pray that this action against them be dismissed and that they be awarded their costs in defending this action and that they be granted such other and further relief as the Court deems just and appropriate.

This 19th day of November, 2015.

s/Richard B. North, Jr.
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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that on November 19, 2015, I electronically filed the foregoing with the Clerk of the Court by using the CM/ECF system which will send notification of such filing to all counsel of record.

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